IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

COLON HEALTH CENTERS OF AMERICA, LLC, and WASHINGTON IMAGING ASSOCIATES—MARYLAND, LLC (d/b/a PROGRESSIVE RADIOLOGY), Plaintiffs, vs. BILL HAZEL, in his official capacity as Secretary of Health and Human Resources, *et al.*, Defendants.	Civil Action No. 1:12-cv-615-CMH-TCB Assigned to the Honorable Judge Hilton

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

INSTITUTE FOR JUSTICE
William H. Mellor*
Robert J. McNamara
Darpana M. Sheth*
901 North Glebe Road, Suite 900
Arlington, VA 22203
wmellor@ij.org, rmcnamara@ij.org, dsheth@ij.org
Tel: (703) 682-9320
Fax: (703) 682-9321

Attorneys for Plaintiffs

*Admitted *Pro Hac Vice*

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Pursuant to Federal Rule of Civil Procedure 56, Local Civil Rule 56(B) for the United States District Court for the Eastern District of Virginia, Plaintiffs Colon Health Centers of America, LLC ("Colon Health Centers") and Washington Imaging Associates—Maryland, LLC ("Progressive Radiology") (collectively, "Plaintiffs") respectfully submit this Memorandum in Support of Plaintiffs' Motion for Summary Judgment.

STATEMENT OF UNDISPUTED MATERIAL FACTS

1. Plaintiff Colon Health Centers is an out-of-state medical provider. (Declaration of Robert J. McNamara ("McNamara Decl."), Ex. 1, RFA No. 32.) Colon Health Centers is incorporated outside the Commonwealth of Virginia, and more relevantly, it maintains its principal place of business outside the Commonwealth of Virginia. (*See* Declaration of Mark Baumel ("Baumel Decl.") ¶ 23; McNamara Decl., Ex. 2.)

2. Plaintiff Progressive Radiology is also an out-of-state medical provider. (McNamara Decl., Ex. 1, RFA No. 38.) Progressive Radiology is incorporated outside the Commonwealth of Virginia, and more relevantly, it maintains its principal place of business outside the Commonwealth of Virginia. (*See* Declaration of Mark Monteferrante ("Moteferrante Decl.") ¶¶ 10-11 & n.1.)

3. Defendants and their official successors under Federal Rule of Civil Procedure 25(d) are state officials acting under color of state law for purposes of administering Virginia's medical certificate-of-public-need program (called Virginia's "CON" requirement below). (McNamara Decl., Ex. 3, RFA No. 1.) All have been sued in their official capacities. (*See* Compl. ¶ 16.)

4. Outside Virginia, both Plaintiffs operate specialized centers or clinics that offer medical imaging services. Colon Health Centers operates a specialized center in Delaware that

provides computed tomographic ("CT") scanning and has partnered with gastrointestinal physicians to offer this service in New Jersey. (*See* Baumel Decl. ¶ 23.) Computed tomography or "CT" is a noninvasive imaging technology that "uses computer analysis of a series of cross-sectional scans made along a single axis of a bodily structure or tissue to construct an image of that structure." (12 Va. Admin. Code § 5-230-10; *see also* Baumel Decl. ¶ 12; *Colon Health Centers of Am., LLC v. Hazel*, 733 F.3d 535, 541 (4th Cir. 2013).) Colon Health Centers uses this CT technology to provide "Integrated Virtual Colonoscopy," a process that provides a "one-stop shop" that screens, diagnoses, and treats colorectal cancer, all within a single appointment. (*See* Baumel Decl. ¶¶ 12, 16–20; *see also id.* ¶¶ 8-15 (describing differences among traditional colonoscopy, virtual colonoscopy, and Integrated Virtual Colonoscopy).)

5. Colon Health Centers believes that there is a need for Integrated Virtual Colonoscopy in Virginia and that nothing like Integrated Virtual Colonoscopy is available in Virginia, despite the fact that nearly 1,400 Virginians die from colon cancer every year. (McNamara Decl., Ex. 4). Colon Health Centers would partner with Virgina-based physicians to begin offering Integrated Virtual Colonoscopy, but for the fact that neither Colon Health Centers nor any potential partner physician can buy the requisite CT scanner without undergoing the burdensome, expensive, and unpredictable CON process. (Baumel Decl. ¶¶ 25-47, 50.).

6. Progressive Radiology operates specialized centers in Maryland and the District of Columbia that provide magnetic resonance imaging ("MRI"). (*See* Declaration of Mark Monteferrante ("Monteferrante Decl.") ¶¶ 10-12, 15.) "Magnetic resonance imaging" or "MRI" means a noninvasive imaging technology "using a nuclear spectrometer to produce electronic images of specific atoms and molecular structures in solids, especially human cells, tissues and organs." (12 Va. Admin. Code § 5-230-10; *see also* Monteferrante Decl. ¶¶ 14-15.)

7. Progressive Radiology has concrete plans to open a new MRI office in Fairfax County near its former Tyson office in order to continue to serve the patients of Virginia with its specialty in orthopedic and neurological imaging. (*See* Monteferrante Decl. ¶¶ 23-27.)

8. The proposed office would include an MRI scanner, costing approximately $1.7 million. (Monteferrante Decl. ¶ 24.) Dr. Monteferrante, Progressive Radiology's managing partner, estimates that the cost of building and furnishing the office would run approximately $500,000 and the projected monthly expenses and costs of operation would be between $50,000 and $100,000. (*Id.*) Based on his prior experience in the Virginia market, Dr. Monterferrante estimates that the new office would serve approximately 400 patients per month. (*Id.* ¶ 25.)

9. To move forward with this plan to open a new imaging office in Virginia, Progressive Radiology would be required to obtain a certificate of need under Virginia's CON program. (Monteferrante Decl. ¶ 27.)

10. Both Dr. Baumel and Dr. Monteferrante have first-hand experience with the review process under Virginia's CON program. (*See* McNamara Decl., Ex. 1, RFA Nos. 45 & 46.) This experience—specifically the expense, duration, and uncertainty of the CON process—makes each unwilling to make further attempts at medical investment in Virginia unless the CON obstacle is first removed. (*See* Baumel Decl. ¶¶ 25-47, 50; Monteferrante Decl. ¶¶ 28-37.) But for that obstacle, both would be moving forward with concrete plans to invest and import medical equipment into Virginia. (*See* Baumel Decl. ¶¶ 43-47, 50; Monteferrante Decl. ¶ 23-27, 34-37.)

Virginia's CON Program

11. Virginia's CON program "is a regulatory program administered by the Virginia Department of Health." (Va. Dep't of Health, 2011 Annual Report on the Status of Virginia's

Medical Care Facilities Certificate of Public Need Program at 1, *available at* http://leg2.state.va.us/dls/h&sdocs.nsf/By+Year/RD712012/$file/RD71.pdf.)

12. The Virginia Department of Health's Office of Licensure and Certification administers Virginia's CON program through its Division of Certificate of Public Need ("DCOPN"). (*See* Compl. ¶ 35; Answer ¶ 35; *see also* McNamara Decl., Ex. 1, RFA No. 80.)

13. Under this program, all medical "projects" require a prior determination by the State Health Commissioner that there is a public need for the project. *See* Va. Code. § 32.1-102.3(A) ("No person shall commence any project without first obtaining a certificate issued by the [State Health] Commissioner. No certificate may be issued unless the Commissioner has determined that a public need for the project has been demonstrated.").

14. Specifically, Virginia imposes a CON requirement on nine different categories of "project." *See* Va. Code § 32.1-102.1 (defining "project"). Most relevant to this lawsuit, "projects" requiring a certificate of need include:

- "Establishment of a medical care facility";
- "Introduction into an existing medical care facility of any new . . . computed tomographic (CT) scanning . . . magnetic resonance imaging (MRI) . . . [or] nuclear medicine imaging, except for the purpose of nuclear cardiac imaging . . . which the facility has never provided or has not provided in the previous 12 months[ ]"; and
- "The addition by an existing medical care facility of any medical equipment for the provision of . . . computed tomographic (CT) scanning . . . [or] magnetic resonance imaging (MRI) . . . ."

Va. Code § 32.1-102.1.

15. Virginia's CON statute also enumerates the types of medical care facilities subject to review, including "[s]pecialized centers or clinics or that portion of a physician's office developed for the provision of outpatient or ambulatory surgery . . . computed tomographic (CT-

scanning, . . . magnetic resonance imaging (MRI) . . . [or] nuclear medicine imaging, except for the purpose of nuclear cardiac imaging." Va. Code § 31.1-102.1 (subsection 9 of definition of "Medical care facility").

16. Under the Virginia CON statute, providing "nuclear cardiac imaging" does not require a certificate of need. (Va. Code § 31.1-102.1; *see also* McNamara Decl., Ex. 3, RFA No. 9.)

17. Virginia's CON requirement applies to CT scanning and MRI projects regardless of the capital cost of the project—purchasing a new CT scanner or MRI machine at any price requires a certificate. (*See* McNamara Decl., Ex. 6, at 12:16-24*;* McNamara Decl., Ex. 1, RFA Nos. 61 & 72.)

18. Virginia's CON requirement applies to the purchase of a new CT scanner or MRI machine regardless of whether the imaging equipment is being used for non-diagnostic purposes such as screening, and regardless of whether the equipment is devoted to a particular body part or particular specialized use. (*See* McNamara Decl., Ex. 1, RFA Nos. 75, 76, & 77.)

19. Virginia's CON requirement applies to projects, as defined by Va. Code § 32.1-102.1, even if the project is entirely privately financed and does not involve any public money from the Commonwealth of Virginia. (McNamara Decl., Ex. 3, RFA No. 4.)

20. Under the Virginia CON statute's definitions of projects and medical care facilities, Plaintiffs must obtain a certificate of need to operate newly purchased medical imaging equipment that is not purchased to replace similar equipment which is currently in operation under a certificate of need. (*See* Compl. ¶ 42; Answer ¶ 42.)

21. Plaintiffs would not be required to obtain a certificate of need to offer imaging services if they were employed by a Virginia-based medical care provider facility with an

existing certificate of need for those services. (*See* McNamara Decl., Ex. 3, RFA No. 8; McNamara Decl., Ex. 1, RFA No. 44.)

22. Virginia requires a certificate of need irrespective of whether all the medical services to be offered would be provided by medical providers licensed by the Commonwealth of Virginia. (McNamara Decl., Ex. 1, RFA No. 74; *see also* McNamara Decl., Ex. 3, RFA No. 3.)

23. Replacement of existing equipment does not require a certificate of need. (Va. Code § 32.1-102.1 (subsection 7 of definition of project); *see also* McNamara Decl., Ex. 3, RFA No. 10; McNamara Decl., Ex. 1, RFA No. 71.)

24. Notably, Virginia also exempts from the CON requirement the introduction of CT scanning into dentists' offices for the purpose of dental imaging. (*See* McNamara Decl., Ex. 1, RFA No. 69; McNamara Decl., Ex. 5, at 13:6-12.) Although the Department of Health does not specifically track the number of CT scanners used in dental offices versus the number of CT scanners used in physician offices, there are 122 cone-beam dental CT scanners currently in Virginia, all of which did not require a certificate of need. (McNamara Decl., Ex. 6.)

25. Similarly, Virginia does not require a certificate of need before the introduction of CT scanning into veterinary offices for the purposes of veterinary imaging. (*See* McNamara Decl., Ex. 1, RFA No. 70; McNamara Decl., Ex. 5, at 13:6-12.) In contrast to the Virginia CON statute's express exemption for nuclear cardiac imaging, the above-identified exemptions for dentist and veterinarian offices are the result of agency interpretation of the statute. (*Compare* Va. Code § 32.1.102.1 ("'Medical Care facility' shall also not include that portion of a physician's office dedicated to providing nuclear cardiac imaging."); *and id.* (defining "project" to include "[i]ntroduction into an existing medical care facility of any . . . nuclear medicine imaging, except for the purpose of nuclear cardiac imaging"), *with* McNamara Decl., Ex. 5, at

13:10-12; 14:24-25; 15:1-9,16-19 (interpreting physician's offices to not include dental and veterinarian offices).) The Department of Health has no knowledge of any policy justification for these exemptions. (*See* McNamara Decl., Ex. 5, at 14:2-3,7-8,10-12,15; 15:10-12,14.)

26. In determining whether a public need for a project has been demonstrated, the State Health Commissioner must consider a list of eight factors, some of which include multiple sub-parts, no one of which is controlling. (*See* Va. Code § 32.1-102.3(B).)

27. The burden is on applicants to produce information and evidence that the proposed project meets these statutory criteria, and thereby demonstrate a public need for the project. (12 Va. Admin. Code § 5-230-40(B); *see also, e.g.*, McNamara Decl., Ex. 7, at 129:15-25; 130:1-5,7-17.)

28. In determining whether a proposed project related to CT or MRI services is consistent with the State Medical Facilities Plan (one of the required statutory criteria for considering an application), the Department of Health does not take into account whether a CT scanner or MRI is devoted to a particular body part or particular specialized use. (*See* McNamara Decl., Ex. 1, RFA No. 77.)

29. Because not all of the statutory factors must be satisfied and no one factor is controlling, the Commissioner possesses a vast amount of discretion in determining whether or not to grant a certificate of need. (*See, e.g.*, McNamara Decl., Ex. 7, at 123:19-25; 124:1-12; 132:1-5, 12-14; 135:19-25; 136:4-6; 138:16-20; 141:13-17; 142:17-25; & 143:1-9; McNamara Decl., Ex. 8, at 97:21-25; 98:2-5, 8-12; 99:8-11; 100:6-16, 19-25; 101:11-18; 102:5-6,16-18.) Thus, it is impossible for an applicant to predict with certainty whether the State Health Commissioner will approve or deny a proposed project. (*See* McNamara Decl., Ex. 1, RFA No.

68.) Indeed, it is possible to have an application meet all but one of these statutory criteria and still be denied. (*See* McNamara Decl., Ex. 5, at 20:8-11, 14-15.)

30. Commencing any project without the required certificate of need is a misdemeanor, punishable by fines of up to $1,000 for each day a facility is in violation. (McNamara Decl., Ex. 1, RFA No. 67; *see also* Va. Code §§ 32.1-27 & 32.1-27.1)

31. Virginia's CON program seeks to discourage medical investments that Virginia has determined are ill-advised, "based on the understanding that excess capacity or underutilization of medical facilities are detrimental to both cost effectiveness and quality of medical services in Virginia." 12 Va. Admin. Code § 5-230-30(1). To that end, Virginia's CON program attempts to "discourage[ ] the proliferation of services that would undermine the ability of essential community providers to maintain their financial viability." *Id.* § 5-230-30(5).

The Virginia CON Review Process

32. Virginia's CON program is based on reviewing applications to determine need both with respect to the geographic region for the proposed facility or service and with respect to the type of proposed facility or service. *See* Va. Code § 32.1-102.3(B). Thus, Virginia's CON program both divides the healthcare market by geography and by product/services. *See id.*

33. Virginia's CON program reviews application based on five distinct geographic regions. (*See* Va. Code. §§ 32.1-102.1 & 32.1-122.05; Va. Dep't of Health, 2011 Annual Report on the Status of Virginia's Medical Care Facilities Certificate of Public Need Program at 26 (Appendix E), *available at* http://leg2.state.va.us/dls/h&sdocs.nsf/By+Year/RD712012/$file/RD71.pdf; McNamara Decl., Ex. 9.) Since 2009, however, the Health Systems Agency of Northern Virginia for Health Planning Region II has been the only regional health planning agency that still exists and

continues to participate in the CON review process. (*See* McNamara Decl., Ex. 10, at 175:21-25; 176:1-25; 177:1-19.)

34. In addition to reviewing applications by geographic region, Virginia's Department of Health uses a "batching" process that groups together applications for similar proposed services or facilities to be reviewed in the same cycle. (*See* McNamara Decl., Ex. 1, RFA No. 54; *see also* 12 Va. Admin. Code § 5-220-200.) Each Batch Group has its own review cycle that begins on the tenth day of each month and is supposed to conclude after 190 days. (*See* Va. Code § 32.1-102.6(D); 12 Va. Admin. Code § 5-220-200; *see also* McNamara Decl., Ex. 10, at 178:8-179:1; McNamara Decl. Ex. 11.)

35. Applications for the same or similar services and facilities that are proposed for the same planning district, or same health planning region for projects reviewed on a regional basis, and are in the same batch review cycle are "competing applications." (*See* 12 Va. Admin. Code §§ 5-220-220 & 5-230-10; *see also* McNamara Decl., Ex. 1, RFA No. 53.)

36. The "batching" review process, which groups similar types of applications together in the same review cycle, helps the Department of Health identify competing applications. (McNamara Decl., Ex. 1, RFA No. 54.) In at least some instances, Virginia-based entities appear to submit "competing" applications for tactical reasons, in order to increase their ability to object to or otherwise block an application they would like to see denied. (Declaration of Arun Singh ("Singh Decl.") ¶ 13.)

Applying for a CON

37. As detailed in the flowchart prepared by the Virginia Department of Health's Division of Certificate of Public Need, Virginia's CON program involves a multi-tiered process"

before various subdivisions within the Department of Health. (*See* Compl. ¶ 118 & App. A; Ans. ¶ 118; McNamara Decl., Ex. 10, at 79:8-25; 80:1-25; 81:1-5, 8-10.)

38. The application process under Virginia's CON program is the same for all projects, regardless of capital costs, with the sole exception of nursing homes. (McNamara Decl., Ex. 1, RFA No. 72; *see also* McNamara Decl., Ex. 5, at 17:22-25 & 18:1-12.)

39. The application process for obtaining a certificate of need is not related to the application process for licensure as a doctor, nurse, or other medical care provider by the Commonwealth of Virginia. (McNamara Decl., Ex. 3, RFA No. 3.)

40. By statute, the application process under Virginia's CON program, as described in the underlying statute and summarized in Appendix A to the Complaint in this action, is supposed to take 190 days from the acceptance of a complete application to the issuance of a final decision by the State Health Commissioner. (*See* Va. Code § 32.1-102.6(D); 12 Va. Admin. Code §§ 5-220-200; McNamara Decl., Ex. 3, RFA No. 22.)

41. While the review process is supposed to take only 190 days, the duration of any particular review process is unpredictable, and in practice it can take much longer. (*See, e.g.*, Baumel Decl. ¶¶ 31, 42 (244 days); Declaration of Dr. Laurence O'Halloran ("O'Halloran Decl.") ¶¶ 17, 20 (1.5 years); Declaration of Dr. William Grant ("Grant Decl.") ¶¶ 12, 16 (12 months); *see also* McNamara Decl., Ex. 3, RFA No. 23.) This is for two reasons.

42. First, the statutory review process only begins at the beginning of the scheduled "batch" period. (*See* Va. Code § 32.1-102.6(D); 12 Va. Admin. Code §§ 5-220-200.) An applicant who wants to import equipment into Virginia therefore must compile his application materials and then wait until the appropriate review cycle begins. (*See id.*)

43. Second, even once the review cycle begins, many applications take longer than 190 days. (*See, e.g.*, Baumel Decl. ¶¶ 31, 42 (244 days); O'Halloran Decl. ¶¶ 17, 20 (1.5 years); Grant Decl. ¶¶ 12, 16 (12 months).) These delays in the process appear to stem almost entirely from Informal Fact-Finding Conferences or IFFCs, which are held in certain applications where the applicant has either received a negative recommendation earlier in the process or where an application has drawn objections or attempted interventions by existing medical providers. (*See* McNamara Decl., Ex. 10, at 67:2-6, 11-14; 190:11-19.) When an informal fact-finding conference is held, the Department of Health (usually through its Adjudication Officer) frequently asks the applicant to voluntarily extend the statutory deadlines. (McNamara Decl., Ex. 12, at 141:18-25; 142:1-6,9-25 & McNamara Decl., Ex. 13,at 3(L); *see also* McNamara Decl., Ex. 5, at 28:11-15.) While the face of the law suggests that these extensions will only happen at the request of an applicant, at least some applicants seem (very reasonably) to believe that they have no choice but to ask for an extension at the Department's behest. (*See* McNamara Decl., Ex. 5, at 28:16-18.). Indeed, the Department is aware of exactly one instance in which an applicant refused to request an extension when prompted, and even that applicant ultimately acquiesced. (McNamara Decl., Ex. 5, at 28:21-25; 29:1-9.)

44. While these IFFCs are nominally open to the public, they are not advertised in any way. (McNamara Decl., Ex. 12, at 272:7-19.) And, despite the "informal" label, this stage of the certificate-of-need process can resemble litigation in court as attorneys regularly participate in these conferences. (*See* McNamara Decl., Ex. 12, at 34:20-24; 99:1-18, 21-25; 100:1-25; 101:1-16; 116:4-21; 123:3-7; 133:3-12;15-19.) Adjudication Officer Doug Harris describes his role within the process of the IFFC as "sort of judge-like." (*See* McNamara Decl., Ex. 12, at 57:1-2.)

45. The Department of Health recognizes that its CON program involves "the complex issue of public need" and that there is an "often voluminous administrative record developed in relation to applications." (McNamara Decl., Ex. 14, at 1.).

46. The CON requirement is not just lengthy, but costly. Even beyond the application fee, most applicants need to hire consultants, attorneys, and other experts in order to put together a successful application. These extra costs run into five or even six figures. (Baumel Decl. ¶¶ 27-31; Monteferrante Decl. ¶¶ 30-32; O'Halloran Decl. ¶¶ 17-20; Grant Decl. ¶¶ 12-13, 17-20; Declaration of Dr. Abbot Byrd ("Byrd Decl.") ¶¶ 9, 11.)

47. When competing applications are reviewed, Virginia's CON program allows preference to be given to certain applicants, including applicants who have "an established performance record in completing projects on time and within the authorized operating expenses and capital costs[.]" 12 Va. Admin. Code § 5-230-60.

48. The Virginia Department of Health's Division of Certificate of Public Need tracks the progress of all CON applications from receipt of a letter of intent to final disposition using a Microsoft Excel spreadsheet, which was produced in discovery in this matter (the "tracking spreadsheet"). This tracking spreadsheet lists all letters of intent received from May 31, 2000 to January 29, 2014 as well as all certificate-of-need applications and final decisions made by the Department of Health on those applications to the best of the Defendants' knowledge. (McNamara Decl., Ex. 15, RFA No. 28.)

49. The dates listed in each row of the tracking spreadsheet are true and correct reflections (to the best of Defendants' knowledge) of the dates on which letters of intent, applications, and final decisions were received or issued by the Defendants. (McNamara Decl., Ex. 15, Defs.' RFA No. 29.)

50. To the extent a row of the tracking spreadsheet indicates an outcome for a particular application (such as the application was withdrawn or granted), that indication is true and correct to the best of Defendants' knowledge. (McNamara Decl., Ex. 15, RFA No. 30.)

51. The Department of Health identifies some CON applicants with a common corporate ownership by assigning those applicants particular numbers that designate the ownership of the applicant. (McNamara Decl., Ex. 5, at 25:7-17, 20-25; 26:1.) These "owner numbers" are assigned by the Department of Health in its sole discretion. *See id*. There is no application process by which a corporation could apply for or seek to be assigned an owner number; instead, the Department decides which applicants are assigned one. *See id*.

52. The version of the tracking spreadsheet produced in Defendants' supplemental production of March 27, 2014, contains a "Corp Codes" tab, which is to the best of Defendants' knowledge an accurate directory of the codes (at the time the codes were assigned) used to represent providers in column A of the tracking spreadsheet. (McNamara Decl., Ex. 15, RFA No. 31.)

53. Not all medical care providers who apply for certificates of need are assigned an owner code like those shown in the tracking spreadsheet. (McNamara Decl., Ex. 15, RFA No. 26.) But those that are assigned an owner number—those that the Department of Health thinks are worth tracking—are much more likely to be successful in applying for a certificate of need than those that haven't been assigned an owner number. (*See* Declaration of Christopher Conover ("Conover Decl.") ¶¶ 12, 99-116.) This is unsurprising, particularly in light of the fact that the Department freely admits that it gives preference to applicants who have previously completed projects in Virginia. (*See supra* ¶ 47.)

54. Virginia has not always had a CON requirement. (McNamara Decl., Ex. 3, RFA No. 5.) For example, from 1989 to 1992, most medical investments (including investments in CT scanners or MRI machines) were removed from the scope of the CON requirement. (*See* McNamara Decl., Ex. 5, at 35:18-25 & 36:1-2.) The Department of Health is aware of no major negative consequences of this deregulation. (*See* McNamara Decl., Ex. 5, at 37:3-10,13.) Some MRI machines and CT scanners in Virginia are still owned and operated without a certificate of need because their purchase dates back to this period of deregulation. (*See, e.g.*, Monteferrante Decl. ¶ 31.)

55. Medical certificates of need were initially mandated by the federal government, but the federal government repealed that requirement in 1986, having concluded that CON requirements in general do not accomplish their stated goals. (*See* McNamara Decl., Ex. 1, RFA Nos. 57 & 58; Compl. ¶¶ 92, 96.) The federal government has reaffirmed its 1986 conclusion that certificate-of-need programs raise costs and harm patients on at least three occasions. First, the Federal Trade Commission ("FTC") send a letter to the Commonwealth of Virginia in 1987, reaffirming these conclusions specifically as to Virginia's CON program. (McNamara Decl., Ex. 18.) Second, a 1988 Staff Report of the Bureau of Economics in the Federal Trade Commission ("FTC") concluded that certificate-of-need programs harm consumers and raise healthcare costs by: (1) serving as a barrier to entry of new healthcare providers; and (2) encouraging hospitals to avoid using more-efficient (but CON-restricted) services and equipment in favor of less-efficient (but CON-free) services and equipment. (McNamara Decl., Ex. 16.)

56. Third, in 2004, the FTC and United States Department of Justice ("DOJ") issued a joint report reaffirming the 1988 study. (*See* McNamara Decl., Ex. 17). Based on 27 days of

joint hearings held from February through October 2003, an FTC-sponsored workshop in September 2002, and independent research (*id.* at 1.), the federal agencies concluded that:

> States with Certificate of Need programs should reconsider whether these programs best serve their citizens' health care needs. The [FTC and DOJ] believe that, on balance, CON programs are not successful in containing health care costs, and that they pose serious anticompetitive risks that usually outweigh their purported economic benefits. Market incumbents can too easily use CON procedures to forestall competitors from entering an incumbent's market. . . . [T]he vast majority of single-specialty hospitals—a new form of competition that may benefit consumers—have opened in states that do not have CON programs. Indeed, there is considerable evidence that CON programs can actually increase prices by fostering anticompetitive barriers to entry. Other means of cost control appear to be more effective and pose less significant competitive concerns.

(*Id.* at 22.)

57. The federal government's general conclusions about medical certificate-of-need regulation are well supported in the academic literature. (*See* Conover Decl. ¶¶ 11, 24-97.) The best interpretation of the whole of that literature is that medical certificate-of-need requirements achieve zero net benefits and impose significant regulatory costs. (*See id.*)

58. For example, medical certificate-of-need requirements do not reduce overall healthcare spending. (Conover Decl ¶¶ 10, 14-23.) This does not necessarily mean that CON requirements have no effect on the distribution of healthcare spending. For example, one study has found that stringent CON requirements are associated with a slight reduction in hospital spending, but not with a reduction in overall medical spending—in other words, that stringent CON requirements can shift spending from one sector (hospitals) to other medical investments. (Conover Decl. ¶ 37.)

59. Virginia is one of 36 states to have some form of medical certificate-of-need requirement, but Virginia is one of only three states that regulate the purchase of new CT scanners or MRI machines without any capital threshold requirement—that is, without reference

to the cost of the machine an applicant wants to purchase. (McNamara Decl., Ex. 1, RFA Nos. 60 & 62; Declaration of Stacy Harshbarger ("Harshbarger Decl.") ¶ 17.)

60. There is an interstate market in both CT scanners and MRI machines. (McNamara Decl., Ex. 1, RFA Nos. 84 & 85.) No CT scanners or MRI machines, however, are manufactured in Virginia. (Declaration of Clark Silcox ("Silcox Decl.") ¶ 4; *see also* McNamara Decl., Ex. 3, RFA Nos. 19, 20 & 21.) These devices, therefore, are exclusively imported into Virginia from out-of-state manufacturers. (*See* Silcox Decl. ¶ 5.)

61. Defendants have no evidence that they are accomplishing anything worthwhile by applying the certificate-of-need requirement to CT scanners and MRI machines without regard for their capital threshold. (*See* McNamara Decl., Ex. 5, at 52:4-25; 53:1-25; 54:1.) They have no evidence of any negative effects in states with no certificate-of-need requirement or states whose certificate-of-need requirements have a minimum capital threshold for CT scanners. (*See* McNamara Decl., Ex. 1, RFA No. 65.) They have no evidence of any negative effects in states with no certificate-of-need requirement or states whose certificate-of-need requirements have a minimum capital threshold for MRI machines. (*See* McNamara Decl., Ex. 1, RFA No. 66.)

62. The results of Virginia's unusual law are predictable: Manufacturers of CT scanners and MRI devices find it far more difficult to export their goods to Virginia than they do to comparable states. (*See* Singh Decl. ¶¶ 7-16; Harshbarger Decl. ¶¶ 15-20.) As a direct result of Virginia's law, approximately $100 million dollars of this equipment has not been imported into Virginia. (Declaration of Jeffrey Klenk ("Klenk Decl.") ¶¶ 17-26.)

63. And Virginia's law imposes these burdens to no good end. The best reading of the available social-science research is that certificate-of-need requirements fail to achieve any of

their stated goals and, far from achieving local benefits, actually achieve net local *costs*. (*See* Conover Decl. ¶¶ 11, 24-97.)

STANDARD OF REVIEW

Summary judgment is appropriate when "there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). Courts should grant summary judgment "[w]here the record taken as a whole could not lead a rational trier of fact to find for the non-moving party . . . ." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (internal quotation marks and citation omitted).

ARGUMENT

Certificate-of-need requirements for medical expenditures are a relic of a failed federal policy—one explicitly recognized as a failure by the federal government, and one that has been successfully abandoned in nearly half the states in the country without any ill effect. Rather than follow suit, however, Virginia has adopted an unusually burdensome form of the law, imposing (without adjustment) its full certificate-of-need burden on the purchase of any enumerated medical-imaging device, no matter how inexpensive.

While states in our federal system enjoy a certain degree of policymaking discretion, that discretion ends where those policies interfere excessively or discriminatorily with the free flow of commerce among the states. *Camps Newfound/Owatonna, Inc. v. Town of Harrison, Me.*, 520 U.S. 564, 571 (1997) (discussing conflicting state commercial regulations as the immediate cause of the forming of a constitutional convention); *C & A Carbone, Inc. v. Town of Clarkstown, N.Y.*, 511 U.S. 383, 390 (1994) ("The central rationale for the rule against discrimination is to prohibit state or municipal laws whose object is local economic protectionism, laws that would excite those jealousies and retaliatory measures the Constitution

was designed to prevent."); *Hughes v. Oklahoma*, 441 U.S. 322, 325-26 (1979) ("[The Commerce Clause] reflected a central concern of the Framers that was an immediate reason for calling the Constitutional Convention: the conviction that in order to succeed, the new Union would have to avoid the tendencies toward economic Balkanization that had plagued relations among the Colonies and later among the States under the Articles of Confederation.").

In an earlier decision in this case, the Fourth Circuit, reversing a prior grant of a motion to dismiss, identified two ways in which Virginia's CON program might run afoul of the dormant Commerce Clause, each of which would hinge on a fact-intensive inquiry. First, it might have the practical effect of discouraging commerce with out-of-state firms. *Colon Health Ctrs. of Am., LLC v. Hazel*, 733 F.3d 535, 544-45; *see also id.* at 547 (noting the possibility that "the bureaucratic red tape foisted upon businesses by the program may well be so cumbersome that, as a functional matter, it imposes a major burden on interstate commerce and discourages out-of-state firms from offering important medical services in Virginia"). Second, it might impose burdens on interstate commerce that outweigh any local benefits under the so-called *Pike* balancing test, under which a law will be struck down if the burden it imposes on interstate commerce is "clearly excessive" in relation to the law's putative local benefits. *Id.* at 545-46; *see also id.* at 546 (noting that the *Pike* test "is fact-bound" (citing *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970)). In practice, courts in this Circuit sometimes blur these two tests,[1] and (recognizing that the factual underpinnings of both claims would be closely related) the Fourth Circuit suggested that discovery should focus primarily on the first claim. *Id.* at 546. It made clear, however, that both claims were viable under the controlling law of this Circuit. *Id.* at 546-47.

[1] *See* Part II, *infra*.

On this record, Plaintiffs are entitled to summary judgment for two independent reasons. First, Virginia's CON requirement violates the dormant Commerce Clause because it actively discriminates against interstate commerce by deliberately shifting investment away from the purchase of new MRI machines and CT scanners (all of which are manufactured outside the state) and toward other, in-state medical expenditures. Second, Virginia's CON requirement runs afoul of the dormant Commerce Clause jurisprudence of the Fourth Circuit as laid out in cases like in *Yamaha Motor Corp. v. Jim's Motorcycle, Inc.*, 401 F.3d 560 (4th Cir. 2005), and *Medigen of Ky., Inc. v. Pub. Serv. Comm'n of W.V.*, 985 F.2d 164 (4th Cir. 1993), both of which make clear that highly unusual, highly discretionary, and highly burdensome permitting systems like Virginia's CON program are unconstitutional unless they are justified by real evidence that they are necessary to achieve some public good.

I. STATES MAY NOT FUND IN-STATE INTERESTS BY IMPOSING COSTS ON OUTSIDERS.

Plaintiffs' first summary-judgment argument rests on three simple, undisputed facts:

- There are no manufacturers of CT scanners or MRI machines in Virginia. *Supra* ¶ 60. In other words, every single new CT scanner or MRI machine purchased for use in Virginia must be imported from an out-of-state manufacturer.
- Virginia's decision to apply its CON requirement to all CT scanners and MRI machines (regardless of their cost) imposes serious burdens on the sale of this equipment and has resulted in nearly $100 million in medical equipment not being imported into Virginia. *Supra* ¶ 62.
- Certificate-of-need requirements like Virginia's do not reduce overall medical expenditures. At most, they move medical expenditures around, decreasing investment in one area (for example, new CT scanners and MRI machines) but

increasing investment in another area (for example, hospital administration). *Supra* ¶ 58.

The consequences of Virginia's application of its CON program to MRI machines and CT scanners (no matter their cost) are unsurprising. An individual who wants to purchase a new CT scanner from an out-of-state manufacturer faces significant costs associated with the CON application process—costs that in many cases can outstrip the cost of the devices themselves. If that same individual redirects his investment elsewhere—by, for example, purchasing an already-existing CT scanner from within Virginia, or contracting with someone in Virginia who already owns a CT scanner, or even just by foregoing CT services and refurbishing his office instead—he can avoid the costs of the CON application. This predictably results in shifting investment away from the purchase of new CT scanners or MRI machines (all of which investment flows to out-of-state manufacturers) and redirecting that money to other Virginia medical services (much or all of which remains in the state).

As explained below, the Supreme Court has repeatedly held that laws operating to disadvantage out-of-state businesses and advantage in-state businesses are deeply suspect under the Commerce Clause. And given that caselaw, one might expect the Defendants in this action to proffer some justification for their decision to deliberately disadvantage the purchase of new CT scanners or MRI machines from their out-of-state manufacturers.[2] One might expect, for example, the Defendants to point to some negative consequence that has occurred in the 47 states that do not have similar CON requirements for inexpensive imaging equipment—but they can point to no such thing. *Supra* ¶ 61. One might expect the Defendants to point to some negative consequence that occurred during the years when Virginia itself had no CON requirement for

[2] To be clear, Virginia has not made a policy decision that CT scanners or MRI machines are themselves unsafe, nor has it made a decision to discourage the *use* of CT scanners or MRI machines. The CON requirement operates only to discourage the acquisition and use of *new* CT scanners or MRI machines.

inexpensive imaging equipment—but, again, they can point to no such thing. *Id*. at ¶¶ 54; 61. Indeed, Defendants can point to nothing beyond the simple assertion that Virginia wants to discourage the purchase of new CT scanner and MRI machines from out-of-state manufacturers and enhance the "financial viability" of existing in-state providers of CT or MRI imaging services. *Supra* ¶ 31. This is not enough.

A law that operates to effectively advantage in-state businesses at the expense of out-of-state businesses violates the dormant Commerce Clause, even if the law itself is nominally even-handed. *See, e.g.*, *C&A Carbone, Inc.*, 511 U.S. at 391 (stating that the "ordinance is no less discriminatory because in-state or in-town processors are also covered by the prohibition"); *Lewis v. BT Inv. Managers, Inc.*, 447 U.S. 27, 39-42 (1980) (rejecting appellant's argument that "the statute ought not to be declared *per se* invalid because it does not prevent all out-of-state investment enterprises from entering local markets"); *accord Colon Health Ctrs.*, 733 F.3d at 544 ("[D]etermining whether Virginia's certificate-of-need law discriminates in either purpose or effect necessarily requires looking behind the statutory text to the actual operation of the law.").

The United States Reports are replete with cases in which the Supreme Court has confronted (and struck down) nominally neutral laws that nonetheless effectively operated to disadvantage out-of-state businesses. In *Bacchus Imports, Ltd. v. Dias*, 468 U.S. 263 (1984), for example, the Supreme Court rejected a Hawaii liquor tax that exempted two things: fruit wine and okolehao (a brandy distilled from an indigenous Hawaiian shrub). *Id.* at 265. The law did not specifically say "locally produced" products were exempt—it simply exempted any fruit wine, and did not exempt locally produced liqueurs—but (as a factual matter) pineapple wine and okolehao were locally produced liquors that were being given a tax advantage over out-of-state liquors that were not exempt. *Id.* at 265, 268-69. While (like here) the burden of the tax

might nominally fall on in-state residents who wanted to purchase the disadvantaged products, the law nonetheless ran afoul of the dormant Commerce Clause because it operated to reduce the ability of out-of-state producers to sell their products. *Id.* at 268-69.

Significantly, the record in *Bacchus Imports* did not contain any evidence that this discrimination actually worked—that is, it contained no evidence that the demand for out-of-state liquors was actually being reduced. Instead, the Court simply held that "as long as there is some competition between the locally produced exempt products and the nonexempt products from outside the State, there is a discriminatory effect." *Id.* at 271. Here, the record is much stronger: Not only is there direct competition between out-of-state manufacturers (who want to sell more CT scanners and MRI machines) and existing in-state providers (who would rather more patients paid to use their existing machines), but the record contains unrebutted expert testimony concluding that the CON requirement is actually working to exclude some $100 million worth of out-of-state imaging equipment from Virginia. *Supra* ¶ 62.

Bacchus Imports is not an anomaly. *See, e.g.*, *W. Lynn Creamery v. Healy*, 512 U.S. 186, 194 (1994) (citing *Bacchus* and noting that "[o]ther cases of this kind are legion"). In *West Lynn Creamery* itself, the Supreme Court confronted a nominally neutral Massachusetts law that imposed costs (in the form of "premium payments") on every "dealer" of milk in the state. *Id.* at 190. The funds generated by these premium payments, though, were then paid directly to Massachusetts dairy farmers. *Id.* at 191. The Supreme Court found this arrangement violated the Commerce Clause because the "premium payments" were "effectively a tax which makes milk produced out of state more expensive." *Id.* at 194. Similarly, here, Virginia law makes it (much) more expensive to purchase CT scanners or MRI machines than it would otherwise be, and this results in would-be purchasers turning to in-state substitute goods, like using existing

CT scanners or MRI machines, all of which (by definition) are either held pursuant to an already-existing certificate of need or have been grandfathered in from the state's period of deregulation. This results in a shift in investment away from out-of-state purchases and toward in-state investment, preventing out-of-state manufacturers from competitively pricing and selling their products as they do in nearly every other state. *Accord Hunt v. Wash. State Apple Adver. Comm'n*, 432 U.S. 333, 350-51 (1977) (holding that North Carolina's requiring apples to display the applicable USDA grade or none at all had a discriminatory effect because it took away "competitive and economic advantages" and "insidiously operate[d] to the advantage of local apple producers"); *see also supra* ¶ 62 (describing effect of CON requirement on sales in Virginia versus the majority of states that do not impose this no-threshold requirement).

Because Virginia's CON requirement for CT scanners and MRI machines (no matter how inexpensive) is intended to[3] and actually does discourage investment in out-of-state devices and encourage spending on in-state medical services, it discriminates against out-of-state commerce. Because the Defendants can adduce literally no evidence that this policy accomplishes anything besides this discrimination, the Plaintiffs are entitled to summary judgment.

II. THIS CASE IS CONTROLLED BY THE FOURTH CIRCUIT'S DECISIONS IN *YAMAHA MOTORS* AND *MEDIGEN*.

Virginia's CON requirements violate the dormant Commerce Clause. They systematically discriminate against new applicants and favor experienced applicants with a past track record of Virginia operations. *See supra* ¶ 47. Courts in the Fourth Circuit, however, frequently avoid the question of whether a law is discriminatory by striking the law down under *Pike* balancing—and this Court can do the same here. Under the Fourth Circuit's decisions in

[3] "[I]t is irrelevant to the Commerce Clause inquiry that the motivation of the legislature was the desire to aid [in-state interests] . . . rather than to harm out-of-state producers." *Bacchus Imports*, 468 U.S. at 273. Whether framed as a desire to provide a benefit to in-state interests or to burden out-of-state interests, the analysis is exactly the same. *Id.*

both *Yamaha Motor Corp. v. Jim's Motorcycle, Inc.*, 401 F.3d 560 (4th Cir. 2005), and *Medigen of Ky. v. Pub. Serv. Comm'n of W.V.*, 985 F.2d 164, 165 (4th Cir. 1993), courts in this Circuit reject unusual, unpredictable, and highly burdensome laws that restrict interstate commerce (like Virginia's CON requirement for inexpensive CT scanners or MRI machines) where there is no record evidence suggesting that the law's burdens are actually necessary to achieve some genuine public benefit. *Cf. Colon Health Ctrs.*, 733 F.3d at 546 (noting that "[t]he *Pike* inquiry, like the discrimination test, is fact-bound"). Under both *Yamaha Motors* and *Medigen*, Virginia's CON requirement for this kind of imaging equipment is unconstitutional, and Plaintiffs are entitled to judgment as a matter of law.

A. Courts In This Circuit Reject Unusual And Unpredictable Laws That Burden Interstate Commerce.

This case bears a close resemblance to *Yamaha Motor Corp.*, where the Fourth Circuit invalidated a Virginia statute under the dormant Commerce Clause that let Virginia motorcycle franchise dealers protest the creation of new franchise dealerships anywhere in the state. 401 F.3d at 563. Recognizing the "chilling effect" of these protest rights on interstate commerce in general and out-of-state interests in particular, the Court noted that "[m]anufacturers incur significant costs, measured in both money and effort, in defending against protests, and this makes an attempt to open a new dealership in Virginia more burdensome than anywhere else." *Id.*at 571. The Court further noted that while "[i]n other states with dealer protection statutes, a manufacturer can reasonably anticipate the regions where it might be susceptible to a protest and can plan its expansion accordingly[,]" in Virginia, the reality was that a "manufacturer ha[d] no way of avoiding" potential protests. *Id.*

Virginia's CON program is no different. The costs of an application are substantial, and the process itself is unpredictable, not just in outcome, but even in duration. The record contains

ample evidence that this cost and unpredictability deters sales of medical equipment in Virginia. *Supra* ¶ 62. Just as in *Yamaha Motor Corp.*, an application can draw an objection from in-state interests, *see* 12 Va. Admin. Code § 5-220-240, but (even worse than in *Yamaha Motor Corp.*) an application can draw a *competing* application from a local provider, which increases the difficulty of the process even further. *Supra* ¶¶ 34-36.

Just as in *Yamaha*, it may well be the case that "those brave enough to try to [complete the process] are likely to be Virginia residents," but that does not alter the fact that applicants are likely to be "outnumbered and outgunned" by well-heeled existing providers. *Yamaha Motor Corp.*, 401 F.3d at 573. The only ways to avoid the CON process are to work with an established Virginia provider who already owns a CT scanner or an MRI machine (either pursuant to a certificate of need or a machine that has been grandfathered in), which (as in *Yamaha*) means that "the major in-state interests affected by the provision[ ] stand to benefit from the law's enforcement." *Id.* And against these local interests, there are no manufacturers of these devices located in Virginia capable of serving as a "political check against the possibility of legislative abuse in the form of . . . laws that unduly burden commerce." *Id.*

Faced with this kind of restriction, the Fourth Circuit held that the law failed *Pike* balancing because the law's "benefits could have been achieved with a less restrictive alternative." *Id.* Here, the number of possible less-restrictive alternatives is enormous—in no small part because, as discussed below, the Defendants have not presented evidence of any local benefits actually being achieved by this requirement. There is no evidence that Virginia could not advance its goals equally well by, for example, imposing a CON requirement on CT scanners or MRI machines over some capital threshold. After all, for obvious reasons, a $100,000 application process is a greater relative burden on someone who wants to buy a $100,000 device

than it is on someone who wants to buy a $10 million device. In the absence of any reason to believe this less-restrictive alternative would achieve all of Virginia's stated goals, the Plaintiffs are entitled to summary judgment in their favor.

B. Courts In This Circuit Require Real Evidence Of Local Benefits Justifying Burdens On Interstate Commerce.

Given the above-described obstacles that Virginia's CON Program imposes on the interstate sale of medical imaging services and devices, "[t]he burden accordingly shifts to the [D]efendant[] to show both that the requirement "'serves a legitimate local purpose' and that this purpose cannot be served by a means less burdensome on interstate commerce." *Medigen of Ky. v. Pub. Serv. Comm'n of W. Va.*, 787 F. Supp. 590, 601 (S.D. W. Va. 1991) (citation omitted) (*Medigen I*).[4] In *Medigen*, the plaintiffs challenged a requirement that medical-waste haulers obtain a "certificate of convenience and necessity" in order to operate anywhere in West Virginia; the district court and Fourth Circuit both held that this requirement violated the dormant Commerce Clause because "the burden on interstate commerce . . . outweigh[ed] the local benefits identified by the Commission." 985 F.2d at 165. Because the Defendant's evidence of local benefits here is even scantier than that proffered by the government in *Medigen*, the Plaintiffs are entitled to judgment as a matter of law.

The district court in that case clearly articulated the government's burden in this context, which cannot be met through mere conjecture or "scant evidence" but instead requires "particularized evidence" of the local benefits being achieved. *Medigen II*, 787 F. Supp at 605. Such evidence, in turn, must "show that a free-market economy will not satisfy the state-wide

[4] The district court in *Medigen* issued two merits opinions. In the first opinion, it laid out the appropriate standard of review and then entered a scheduling order that "provide[d] the parties with an opportunity to present further evidence to the court." *Medigen I*, 787 F. Supp. at 601. It analyzed that evidence in a subsequent opinion. *See Medigen of Ky., Inc. v. Pub. Serv. Comm'n of W. Va.*, 787 F. Supp. 602 (S.D. W. Va. 1992) (*Medigen II*), *aff'd* 985 F.2d 164 (4th Cir. 1993).

need" for the otherwise regulated service. *Id.* at 605. Moreover, if a plaintiff's expert testimony on this point is not effectively "contradicted by expert testimony offered by the defendants or . . . by other particularized evidence," then the court must adopt the plaintiff's evidence. *Id.* at 607. Finally, "[i]n the absence of evidence contradicting . . . alternatives presented by plaintiffs" to a challenged regulation, "defendants fail[] to make even a minimal showing that there are no other means" for achieving the challenged regulation's alleged purpose. *Id.* at 609.

In *Medigen*, the government offered two justifications for its entry restrictions: (1) "insuring that service is available throughout West Virginia at reasonable prices"; and (2) preventing "ruinous" competition that would "result[] in monopolization of the market." 985 F.2d at 167. The district court and the Fourth Circuit rejected both of these because they were unsubstantiated by the evidence. As to the first interest, the Fourth Circuit noted that entry restrictions should generally be assumed to achieve the opposite: that "[r]estricting market entry . . . necessarily *limits* the available service because it limits the number of medical waste transporters from which a medical waste generator can seek service." *Id.* On the same point, the district court observed that there was simply no record evidence demonstrating the existence of a real problem in the medical-waste field, noting that "no infectious medical waste generator, either from within or without the state . . . testif[ied] that services could not be obtained at an affordable rate." *Medigen II*, 787 F. Supp. at 605-06. The district court also rejected the second interest, noting that the state "failed to make even a minimal showing that there [were] no other means of insuring state-wide availability of infectious medical waste transportation services at reasonable rates." *Id.* at 609. And the Fourth Circuit affirmed, holding that there was "no basis in the record . . . for concluding that competition in th[e] [medical waste transportation] market

has had or will have any destructive effects" thus rendering the state's allegation of such effects "entirely speculative." 985 F.2d at 167.[5]

The courts' analysis in *Medigen* controls here. Here, like in *Medigen*, the state's entry controls (CON here; public convenience and necessity there) make it more expensive to acquire CT scanners or MRI machines or offer related services than it would otherwise be. *Cf. Medigen*, 985 F.2d at 167 (finding that "[r]estricting market entry . . . necessarily *limits* the available service"). And Defendants have provided not even a scintilla of evidence that they are achieving any local benefits whatsoever by imposing this burden. There is no evidence that the public would be worse off in Virginia in the absence of this requirement. Indeed, there is no evidence that the public was worse off during the several years in which Virginia rescinded the CON requirement for low-dollar imaging equipment like this. *Supra* at ¶ 54. Nor is there any evidence that the public is any worse off in any of the 47 states that do not impose a similar requirement. *Supra* at ¶¶ 61, 63. Nor can the Defendants make "even a minimal showing that there are no other means" of achieving whatever benefits they believe are generated by restricting investment in low-dollar imaging equipment. *Cf. Medigen II*, 708 F. Supp. at 608.

Indeed, to the extent the record contains any evidence regarding the actual effect of this requirement, that evidence cuts directly against Virginia. The record demonstrates that the CON requirement is successful in reducing the purchase of CT scanners and MRI machines from out-of-state manufacturers, to the tune of roughly $100 million in forgone sales. *Supra* ¶ 62. And the record shows that the best reading of the extensive social-science literature on certificate-of-

[5] While the government in *Medigen* apparently did not directly raise public health or safety in defense of the law, the district court considered (and rejected) that as a possible local benefit regardless. *See Medigen II*, 787 F. Supp. at 606 ("[i]nherent in the state interest purportedly served by the certification requirement is the assumption that the public health and safety [would] be endangered [without the requirement]"). The district court rejected this local benefit as well because once again the government had "offered scant evidence of how the requirement protects the public health, safety and welfare." *Id.*

need requirements in general—much less deeply unusual certificate-of-need requirements like the imaging-equipment restrictions at issue in this motion—shows that these requirements fail to achieve any net benefits for the public at all. *Supra* ¶ 63. In the absence of literally any evidence to contradict this expert testimony or identify real problems that the imaging-equipment restriction addresses, *Medigen* requires this Court to grant the Plaintiffs' motion for summary judgment.

CONCLUSION

For the foregoing reasons, Plaintiffs are entitled to judgment as a matter of law, and Virginia's certificate-of-need requirement for imaging equipment like CT scanners and MRI machines should be enjoined.

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Respectfully submitted,

/s/ Robert J. McNamara
William H. Mellor*
Robert J. McNamara
Darpana M. Sheth*
INSTITUTE FOR JUSTICE
901 North Glebe Road, Suite 900
Arlington, VA 22203
wmellor@ij.org, rmcnamara@ij.org, dsheth@ij.org
Tel: (703) 682-9320
Fax: (703) 682-9321

Attorneys for Plaintiffs

*Admitted *Pro Hac Vice*

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 15th day of August, 2014, a true and correct copy of the MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT was served upon the following counsel of record by electronic mail to:

Stuart A. Raphael
Solicitor General

Trevor S. Cox
Deputy Solicitor General

Christy W. Monolo
Assistant Attorney General

Farnaz Thompson
Assistant Attorney General

Office of the Attorney General
900 East Main Street
Richmond, VA 23219
Email: sraphael@oag.state.va.us; TCox@oag.state.va.us; cmonolo@oag.state.va.us; FThompson@oag.state.va.us.

Attorneys for Defendants

/s/ Robert J. McNamara
Robert J. McNamara
Attorney for Plaintiffs